



**Testimony
Before the Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce
United States House of Representatives**

**Research Policies at the National
Institute of Mental Health**

Statement of

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Mr. Chairman and distinguished members of the Subcommittee: I am Dr. Thomas Insel, the Director of the National Institute of Mental Health (NIMH), the component of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), tasked with responsibility for developing improved methods of diagnosing, treating, and preventing mental disorders, including schizophrenia, autism, and mood and anxiety disorders.

To accomplish this mission, the President and the Congress have provided the NIMH a staff of over 700 employees and a budget of approximately \$1.4 billion for Fiscal Year 2006. Nearly 90% of this budget, or almost \$1.2 billion, is allocated to the support of biomedical research and research training activities through various grant, contract, and fellowship mechanisms at universities, hospitals, and clinics around the nation. The remaining \$160 million per year is used to support a unique and critical intramural biomedical research program on the NIH campus in Bethesda, Maryland. This program was established to provide rapid responses to public health emergencies and to support an environment of innovation and creativity for biomedical discoveries. It is the operation of this intramural research program that is the focus of this hearing today.

First, I want to commend the Committee for its interest in NIH and the NIMH. As a public servant, I am well aware of my responsibilities to be a careful and vigilant steward of the public resources entrusted to my care. I know full well that you share my commitment on this point, and that you are working with all of us at the NIH to uphold the highest standards that can rightfully be expected by the public, whose support has enabled us to make remarkable strides in biomedical science. The Subcommittee has been working with NIH on several important issues and concerns that must be addressed, and I welcome the opportunity to cooperate with you as

you continue to do so. I have already met with Subcommittee staff on three occasions. Based on the information that has been made available to me, I have taken action to improve our management of clinical samples. I am already taking corrective actions.

When I joined the NIMH in November 2002, I was impressed by the level of commitment to patients and families that was clearly so much a part of the culture of the Institute. NIH has been called the “crown jewel” of HHS, and I believe it is such a jewel, among other reasons, because of the dedication and skill of those who conduct research in our intramural program. It is because of them that we have made rapid progress against disabling diseases such as schizophrenia, bipolar illness, and depression. Our stakeholders, especially the families who struggle with these diseases, need us to do all in our power to ensure that science advances as rapidly as possible. At the same time, science—no matter how laudatory its objectives and results—must be conducted with the utmost emphasis on ethical standards, ensuring public trust and support. *This is not negotiable.*

To assure that the science performed at NIMH is of the highest quality and meets stringent ethical standards, there are policies and procedures for the conduct of clinical research, including the management of clinical samples and interactions with industry. We realize that science and public policies change over time and that our rules and procedures must be continually scrutinized for relevance and effectiveness. Although I am confident in the high ethical standards held by our staff, we occasionally find serious problems can occur, as is the case in most large organizations. To the extent that problems result from systemic issues, I am working with the NIH leadership on institutional reforms.

At NIMH we recognize that rapid progress requires collaboration, including the exchange of clinical samples, such as blood or cerebrospinal fluid. As these samples are a non-renewable resource from patients involved in clinical studies, the management of these samples is an important aspect of our stewardship of the public trust. The following points may help the Committee understand our approach to this stewardship:

- Federal regulations require both Institutional Review Board (IRB) approval and informed consent, unless waived by the IRB, before a proposed study involving human subjects can begin.
- Samples derived from clinical studies conducted at the NIH are Government property under the responsibility and accountability of chief of the pertinent Laboratory or Branch. The use of these samples is part of our obligation to research volunteers, who are our partners in the discovery process.
- When a trainee or non-tenured investigator leaves the NIMH, the disposition of the clinical samples collected by that junior investigator remains the responsibility of the Laboratory/Branch chief. When the Laboratory/Branch chief leaves, the disposition of the clinical samples becomes the responsibility of the Institute's Scientific Director, who is also the director of the NIMH Division of Intramural Research Programs.
- Collaboration with non-government scientists in the private sector is encouraged as part of an intramural research scientist's official duty. This means that work with industry is done on official time and without non-government compensation. In the past, consultations with industry were permissible, subject to prior

approval, if no Federal resources were used, no conflict or subject matter overlap with official duties was identified, and no other ethics concerns were present.

- Investigators with potential conflicts of interest are required to disclose these potential conflicts to the IRB as part of the review process. Like all executive branch employees, investigators who conduct clinical research generally may not participate in official matters in which they have a financial interest.
- The exchange of clinical samples may be an important aspect of collaboration. NIH is enhancing policies pertaining to the handling of human tissue samples and related intellectual property. At NIMH, I believe we have not done enough to ensure that all clinical samples leaving from or arriving at the Institute were adequately monitored. And, while the NIH has a variety of possible written mechanisms (including the Cooperative Research and Development Agreement (CRADA), the Material Transfer Agreement (MTA), and the Simple Letter Agreement(SLA)), these mechanisms have not been used uniformly within the NIMH.
- Current policies require that surplus tissue samples from completed studies need to be monitored through continuing IRB review if the samples are linked to patient identifiers. Although all of our intramural scientists engaged in clinical research are required to complete training in human subjects protections, I am concerned that NIMH investigators may not be uniformly aware of when the use of stored samples requires IRB review.

To address these concerns, I have done the following:

- On May 2, 2006, I called an intramural faculty meeting to review current policies and expectations for the handling of clinical samples.
- On May 26, 2006, the NIMH's Acting Clinical Director, Dr. Donald Rosenstein, and I sent a follow-up memo to all intramural scientists to remind them of the current policies and expectations. Specifically, we are requiring that all collaborations involving clinical samples be documented with a written agreement (e.g., CRADA, MTA, or SLA) and that these agreements be cross-referenced for potential conflicts of interest.
- Some of the clinical samples stored at the NIH are from studies that have been completed, meaning that they are no longer enrolling subjects and analyzing data. We are in the process of reviewing all collaborations using stored samples from both active and inactive studies by intramural clinical scientists to ensure that they have appropriate approval and documentation. For stored clinical samples of a completed study, we are requiring all investigators to have an active IRB-approved protocol with continuing review to permit monitoring of these samples.

It is important for the Subcommittee to realize that although standards and policies for clinical research and collaborations with the private sector have changed over time, certain rules of conduct have remained constant. NIH scientists have always been required to abide by the general principles of government service. It is a public trust requiring employees to place the public health over private gain. We need to be sure we provide NIH staff with the tools they need to maintain this high standard.

Mr. Chairman and members of the Subcommittee, thank you for taking the time to look into these issues at the NIH and the NIMH. We are very proud of the accomplishments that have been made by the NIH, and the fundamental and profound role the agency and its scientists have played in alleviating suffering from disease. We are in a unique position because not only do we have to answer to our primary stakeholders—our patients and their families—but we have to answer to you and to every member of the public who has entrusted us with their hard-earned dollars to carry out NIMH’s profound yet straightforward mission: to reduce the enormous burden of mental illness and behavioral disorders through research on mind, brain, and behavior.

I will be pleased to answer any of your questions.